

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,072	02/27/2002	Laurie DeLeve	13761-7065	1401

7590

08/09/2002

Jennifer M. Phelps  
McCutchen, Doyle, Brown & Enersen, LLP  
18th Floor  
Three Embarcadero Center  
San Francisco, CA 94111

EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 08/09/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Applicati n N .

10/086,072

Applicant(s)

DELEVE, LAURIE

Examiner

Mojdeh Bahar

Art Unit

1617

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

## **DETAILED ACTION**

### ***Claim Objections***

Claims 1-2 and 11 are objected to because of the following informalities: the employment of parenthetical expressions “(SOS)” and “(MMP)” is considered informal.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-6, 11-13 and 16 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The MMP inhibitor “doxycycline” is not supported by the specification.

In order to expedite prosecution, examiner has searched and examined the claims as they read on the MMP inhibitor “doxycycline”.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being

Art Unit: 1617

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression, “preventing” in claims 1-17, renders the claims indefinite as failing to clearly set forth the metes and bounds of the patent protection desired. Examples of how and when to prevent SOS or other liver diseases claimed herein are not set forth in the specification. Absent such exemplification, the skilled artisan could not establish the identity of those situations wherein prevention of SOS or other liver diseases would be effected. Furthermore, it is unclear as to the degree of prevention (e.g., total prevention, some prevention, probable prevention, total prevention in most cases...etc.) herein because the specification does not disclose the extent of prevention achieved. Neither is the population that needs prevention of SOS or other liver diseases defined in the specification.

Examiner would favorably consider the term “prophylaxis” over “prevention”.

Claim 10 contains the trademark/trade name RS-130,830, CGS 27023 A, BAY 12-9566, Ro 32-3555, BMS-272591, D2163. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe particular MMPs and, accordingly, the identification/description is indefinite.

Claims 1-6, 10, 11-13 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear what "doyxcycline" is?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 9, 11-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Periostat (doxycycline capsules).

Periostat (doxycycline capsules) teaches twice a day administration of doxycycline to adult patients, see Clinical Study page 945 in particular.

Claims 10 are rejected under 35 U.S.C. 102(b) as being anticipated by McKearn et al. (WO 00/38717).

McKearn et al. (WO 00/38717) teaches a method comprising employing matrix metalloproteinase inhibitor in combination with radiation therapy, see abstract in particular. McKearn et al. (WO 00/38717) further teaches the following MMPs specifically: Marimastat, Metastat, Bay-12-9566 and D-2163, see page 71 for example.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1617

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-6, 9, 11-13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Periostat (doxycycline capsules).

Periostat (doxycycline capsules) teaches the administration of 20 mg twice a day of doxycycline to adult patients, see Clinical Study page 945 in particular.

Periostat (doxycycline capsules) does not teach the administration of 15 mg twice daily of doxycycline to adult patient.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer 15 mg twice daily of doxycycline to adult patient.

One of ordinary skill in the art would have been motivated to administer 15 mg twice daily of doxycycline to a patient because optimization of amounts is within the skill of the artisan and is therefore obvious.

Claims 4, 7-10, 14-15 and 17 are rejected under 35 USC 103 as being unpatentable over McKearn et al. (WO 00/38717) and Watanabe et al. (USPN 6,150,394).

McKearn et al. (WO 00/38717) teaches a method comprising employing matrix metalloproteinase inhibitor in combination with radiation therapy, see abstract in particular.

McKearn et al. (WO 00/38717) further teaches the following MMPs specifically: Marimastat, Metastat, Bay-12-9566 and D-2163, see page 71 for example.

Watanabe et al. (USPN 6,150,394) teaches a method comprising administering 0.01 mg/kg/day to 100 mg/kg/day of compositions comprising MMPs of formula I (which encompass 2-[(4-biphenylsulfonyl)amino]-3-phenyl-propionic acid), see col. 19, lines 13-35. Watanabe also teaches that its compositions can be administered parenterally, see col. 19, lines 37-47.

McKearn et al. (WO 00/38717) and Watanabe et al. (USPN 6,150,394), taken together do not specifically teach the 100-200 mg/hour administration of 2-[(4-biphenylsulfonyl)amino]-3-phenyl-propionic acid in their methods of administering MMPs.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer 100-200 mg/hour of 2-[(4-biphenylsulfonyl)amino]-3-phenyl-propionic acid to the patient.

One of ordinary skill in the art would have been motivated to administer 100-200 mg/hour of 2-[(4-biphenylsulfonyl)amino]-3-phenyl-propionic acid to a patient because optimization of amounts is within the skill of the artisan and is therefore obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

Art Unit: 1617

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
August 5, 2002

  
RUSSELL TRAVERS  
PRIMARY EXAMINER  
GROUP 1200